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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/164,223	09/30/1998	ALEXANDER GAIGER	210121	6400

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EXAMINER

SCHWADRON, RONALD B

ART UNIT

PAPER NUMBER

1644

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27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/164,233	Applicant(s) Gaiger et al.
Examiner Ron Schwadron, Ph.D.	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10 and 23-112 is/are pending in the application.
- 4a) Of the above, claim(s) 10, 23-103, and 106 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 104, 105, and 107-112 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

1. Claims 104,105,107-112 are under consideration. Claims 104,107-112 have been amended. Claim 105 is rejoined now that applicant has amended claim 104 such that it is free of the prior art.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 104,105,110-112 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides.

The instant claims encompass a variant peptide with one to three substitutions wherein said peptide encodes an immunogenic peptide wherein said peptide binds MHC of an animal (eg. T cell binding requires MHC binding of the peptide). There are thousands of different mammals that express structurally differing MHC molecules that bind different, largely nonoverlapping sets of peptides and the specification provides written description

of variants only derived from mouse or human. In addition, regarding claims that encompass immunogenic peptides which bind human MHC, the art recognizes that there are hundreds of different allotypes of MHC molecules found in humans, wherein each allotype binds a unique set of peptides not bound by a different allotype. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the specification has disclosed specific immunogenic peptides which bind MHC, while claiming peptides which bind any MHC from any mammal. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, the rejection as enunciated in the previous Office Action was intended for the pending claims and erroneously listed claims not under examination in the instant application. Regarding applicants comments, attention is directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. The art recognizes that different MHC molecules bind largely nonoverlapping sets of peptide derived from a particular peptide wherein the ultimate identity of said peptides is empirically determined (see Deavin et al., page 145). In the instant case, SEQ. ID. NO. 2 has been identified as a peptide that binds certain MHC class I alleles. However, there is no disclosure in the specification as to the identity of amino acids which can be substituted and wherein the peptide still retains ability to bind said MHC class I alleles. There is no disclosure in the specification as to what amino acids would be altered to permit binding of said peptide to MHC alleles not disclosed in the specification. The instant claims encompass a variant peptide with one to three substitutions wherein said peptide encodes an immunogenic peptide wherein said peptide binds MHC of an animal (eg. T cell binding requires MHC binding of the peptide). There are thousands of different mammals that express structurally differing MHC molecules that bind different, largely nonoverlapping sets of peptides and the specification provides written description of variants only derived from mouse or human. In addition, regarding claims that encompass immunogenic peptides which bind human MHC, the art recognizes that there are hundreds of different allotypes of MHC molecules found in humans, wherein each allotype binds a unique set of peptides not bound by a different allotype. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the

invention claimed herein.

4. Claims 107-112 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "composition" in claims 108-112. While the specification discloses vaccines with the ingredients recited in claims 108-112 (eg. non-specific immune response enhancer), there is no disclosure of non-vaccine compositions in the specification as originally filed which contain a non-specific immune response enhancer. These two terms differ in scope in that the art recognizes that a vaccine is used for treatment of disease, including human disease, while the term composition does not necessarily imply that the composition would be used to treat human disease. There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

5. Claims 107 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to use the instant invention for the treatment of cancer *in vivo* in humans. The specification discloses that the claimed pharmaceutical composition is used for the treatment of cancer in humans. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass a pharmaceutical composition for the treatment of cancer *in vivo* in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence whether the claimed compositions can be used for treatment of cancer *in vivo* in humans. The specification discloses no working examples with regards to the use of the instant invention for the treatment of disease *in vivo* in humans.

Regarding the *in vivo* mouse data disclosed in the specification, Boon teaches that it is unclear whether tumor derived peptides can be used to treat human cancer. Boon discloses that a variety of potential problems exist that could prevent therapeutic

application of tumor peptide vaccines in humans (eg. loss of tumor antigens and/or MHC expression by variant tumors in vivo can result in tumors which are refractory to killing by cytotoxic cells (see page 178, second column, second paragraph)). Furthermore, the aforementioned tumor antigens already occur in patients, yet are insufficient to render an antitumor response in vivo.

Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. Se(CAFC 1988).

Regarding applicants comments, the only disclosed use for a composition containing a "pharmaceutically acceptable carrier or excipient" in the specification is treatment of disease in humans.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 105,109,111,112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 105 is indefinite in that it lacks antecedent basis in claim 104 in the recitation of "react with WT1 specific antisera". Claims 109 and 111 lack antecedent basis in the recitation of " immune response enhancer" because the claims which they depend from recite " non-specific immune response enhancer".

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee

pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600

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Art Unit 1644